June 2, 2023

CorNeat Vision Ltd.
Gilad Litvin, M.D.
Chief Medical Officer
4 Hasheyzaf St.
Raanana, 4366411
Israel

Re: K223074
Trade/Device Name: CorNeat EverPatch
Regulation Number: 21 CFR 886.3130
Regulation Name: Ophthalmic Conformer
Regulatory Class: Class II
Product Code: QWU
Dated: May 5, 2023
Received: May 5, 2023

Dear Gilad Litvin, M.D.:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Claudine H. Krawczyk -S

Claudine Krawczyk
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223074

Device Name
CorNeat EverPatch

Indications for Use *(Describe)*
The CorNeat EverPatch is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This 510(k) summary of safety and effectiveness information, provided on the following pages, is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APPLICANT:	CorNeat Vision, Ltd. 4 Hasheizaf st. Raanana, Israel 4366411
OFFICIAL CORRESPONDENT:	Dr. Gilad Litvin Chief Medical Officer +972 50-351-4057 gilad@corneat.com
DATE SUMMARY PREPARED:	June 2, 2023
TRADE/MODEL NAME:	CorNeat EverPatch
COMMON NAME:	Prosthesis, eyelid spacer/graft, polymer
DEVICE CLASSIFICATION / CODE	21 CFR 886.3130, Class II QWU
PREDICATE DEVICE:	KeraSys Bioengineered Lamellar Patch Graft K090078 (May 8, 2009)
REFERENCE DEVICES:	Neuro-Patch K960470 (May 10, 1996); PowerFlow™ Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex™ Catheter K163001 (April 17, 2017)

DEVICE DESCRIPTION

The CorNeat EverPatch is a synthetic, tissue-integrating surgical matrix made of non-degradable polymer fibers. The EverPatch includes 6 bio-stitching holes which are intended to anchor the device by facilitating direct conjunctival adhesion to the sclera thus supporting its bio-integration. The holes at each corner can also be used to suture the device to the sclera.

INDICATIONS FOR USE

The CorNeat EverPatch is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

Both the subject device and predicate are intended to reinforce sclera and aid the physical

reconstruction of the ocular surface. The subject and predicate devices are based on the following same technological elements: Intended use, placement technique and anatomical site, sterility, packaging, sterilization, and biocompatibility.

The differences between the subject device and cited predicate include:

- Dimensions: The CorNeat EverPatch is slightly thinner and smaller than the predicate device, the thickness is similar for its intended use. The CorNeat EverPatch is sized to be used as supplied and should not be trimmed.
- Materials: The CorNeat EverPatch is comprised of aromatic poly(carbonate-urethane) which differs from the material used in the predicate. EverPatch material has demonstrated biocompatibility from testing conducted per ISO 10993-1 as the predicate device. Non-degradable, bio durable polymers have been used in the following reference devices for other applications for long-term intravascular catheters (K163001) and dura substitute in neurological procedures (K960470).

The following table shows a comparison of the technological characteristics between the CorNeat EverPatch and the cited predicate.

TABLE 1
TECHNOLOGICAL COMPARISON OF THE CORNEAT EVERPATCH TO THE PREDICATE DEVICE

Characteristic	CorNeat EverPatch (Subject Device)	KeraSys Bioengineering Lamellar Patch Graft K090078 (Predicate Device)	Comparison
Manufacturer	CorNeat Vision, Ltd.	IOP, Inc.	N/A
Regulation/Product Code	21 CFR 886.3130; QWU, Prosthesis, Eyelid Spacer/Graft, polymer	21 CFR 886.3130; NXM, Prosthesis, Eyelid Spacer/Graft	N/A
Intended use	To reinforce sclera and aid the physical reconstruction of the ocular surface.	To reinforce sclera and aid the physical reconstruction of the ocular surface.	Same
Target Population	Patients undergoing ocular surgery in need of scleral reinforcement	Patients undergoing ocular surgery in need of scleral reinforcement	Same
Indications for use	The EverPatch is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface.	The KeraSys Bioengineered Lamellar Patch Graft is intended for implantation to reinforce sclera and aid the physical reconstruction of the ocular surface.	Same
Anatomical Sites	Ocular Surface	Ocular Surface	Same
Use Environment	Surgical (Rx Only)	Surgical (Rx Only)	Same
Characteristics			
Material	Aromatic Polycarbonate urethane	Processed porcine submucosa	Different but not raising different questions of safety and effectiveness
Supplied	Sterile	Sterile	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Recommended Usage	Single Use	Single Use	Same
Physical Dimensions	0.5 cm x 0.65 cm with 100 microns thickness	1 cm x 1.5 cm with 150 microns thickness (hydrated)	Different but not raising different questions of safety and effectiveness

Characteristic	CorNeat EverPatch (Subject Device)	KeraSys Bioengineering Lamellar Patch Graft K090078 (Predicate Device)	Comparison
Fundamental Technology	Prefabricated material of fixed dimensions to reinforce sclera and aid the physical reconstruction of the ocular surface.	Prefabricated material of fixed dimensions to reinforce sclera and aid the physical reconstruction of the ocular surface.	Same
Fundamental Technology	The CorNeat EverPatch is sized to be used as supplied and should not be trimmed.	The device can be trimmed to size.	Different but not raising questions of safety and effectiveness.
Fundamental Technology	The device can be sutured in place without cheese-wiring.	The device can be sutured in place without cheese-wiring.	Same
Treatment Plan Prescription or OTC	Rx Only	Rx Only	Same

PERFORMANCE DATA

Bench Testing

Biocompatibility evaluations were completed per ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing for externally communicating, blood contacting, permanent devices and FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The following were evaluated:

- Cytotoxicity
- Maximization Sensitization
- Ocular Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Implantation 13 weeks
- Chemical Characterization
- Subacute/ Sub-chronic Toxicity
- Subacute/ Chronic Toxicity
- Genotoxicity

Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30.

The following tests were performed:

- Dimensional Analysis
- Cheese-wiring
- Mechanical properties
- Sterilization
- Packaging Validation
- Shelf-life
- Pyrogenicity – Bacterial Endotoxin Test (LAL)
- Ocular implantation animal study

Clinical Performance Evaluation

Clinical data is not required to demonstrate substantial equivalence.

CONCLUSION

The subject device, CorNeat EverPatch, has the same intended use as the cited predicate device. Testing performed on the subject device demonstrates the device meets the requirements and is substantially equivalent to the predicate.